General Assembly

Raised Bill No. 5212

February Session, 2010

LCO No. **348**

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Referred to Committee on Insurance and Real Estate

Introduced by:
(INS)

AN ACT CONCERNING INSURANCE COVERAGE FOR THE TREATMENT OF BLEEDING DISORDERS.

Be it enacted by the Senate and House of Representatives in General Assembly convened:

Section 1. (NEW) (*Effective January 1, 2011*) As used in sections 1 to 4, inclusive, of this act:

(1) "Ancillary infusion equipment and supplies" means the equipment and supplies required to infuse a blood clotting product into a human vein, including, but not limited to, syringes, needles, sterile gauze and alcohol swabs, tourniquets, medical tape, sharps or equivalent biohazard waste containers, and cold compression packs.

(2) "Bleeding disorder" means a medical condition characterized by a deficiency or absence of one or more essential blood clotting proteins in the human blood, including, but not limited to, all forms of hemophilia, Von Willebrand disease and other bleeding disorders that result in uncontrollable bleeding or abnormal blood clotting.

(3) "Blood clotting product" means an intravenously administered medicine manufactured from human plasma or recombinant

biotechnology techniques, approved for distribution by the federal Food and Drug Administration and used for the treatment and prevention of symptoms associated with bleeding disorders. The term includes, but is not limited to:

(A) Factor VIIa, Factor VIII and Factor IX products;

(B) Von Willebrand Factor products;

(C) Prothrombin complex concentrates;

(D) Activated prothrombin complex concentrates; and

(E) Other products approved by the federal Food and Drug Administration for the treatment of bleeding disorders and associated inhibitors.

(4) "Clinical coagulation laboratory" means a clinical laboratory, licensed pursuant to section 19a-30 of the general statutes, that is capable of diagnosing bleeding disorders and performing specialized coagulation studies of human blood for patients with bleeding disorders.

(5) "Hospital" means an establishment for the lodging, care and treatment of persons suffering from disease or other abnormal physical or mental conditions and includes inpatient psychiatric services in general hospitals.

Sec. 2. (NEW) (*Effective January 1, 2011)* (a) Each individual health insurance policy providing coverage of the type specified in subdivisions (1), (2), (4), (11) and (12) of section 38a-469 of the general statutes delivered, issued for delivery, renewed, amended or continued in this state:

(1) If providing coverage for outpatient prescription drugs approved by the federal Food and Drug Administration, shall provide coverage for:

(A) All blood clotting products, approved by the federal Food and Drug Administration and prescribed by an insured's treating physician, in multiple assay ranges as applicable, including from a 340B Program affiliated with a hemophilia treatment center. No vendor, pharmacist or provider shall make any substitution for a blood clotting product without the prior approval of such treating physician;

(B) All ancillary infusion equipment and supplies, including from a 340B Program affiliated with a hemophilia treatment center; and

(C) Nursing services provided in the home setting to assist an insured in the reconstitution and administration of blood clotting factors;

(2) Shall provide coverage for physician services for the treatment of bleeding disorders provided to an insured with a bleeding disorder or a suspected bleeding disorder and for services provided at a hemophilia treatment center to such insured for such treatment; and

(3) Shall provide coverage for clinical laboratory services at a clinical coagulation laboratory that an insured's treating physician determines are medically necessary for the screening, diagnosis and treatment of a bleeding disorder or a suspected bleeding disorder.

(b) If an insurer, health care center or other entity providing coverage of the type specified in subsection (a) of this section requires preauthorization for such blood clotting products, such insurer, health care center or other entity shall complete the preauthorization not later than twenty-four hours or one business day, whichever is later, from the time or date the insurer, health care center or other entity receives the preauthorization request. If the circumstances are deemed urgent by the insured's treating physician, the insurer, health care center or other entity shall provide the preauthorization upon request by such physician.

Sec. 3. (NEW) (*Effective January 1, 2011)* (a) Each group health

insurance policy providing coverage of the type specified in subdivisions (1), (2), (4), (11) and (12) of section 38a-469 of the general statutes delivered, issued for delivery, renewed, amended or continued in this state:

(1) If providing coverage for outpatient prescription drugs approved by the federal Food and Drug Administration, shall provide coverage for:

(A) All blood clotting products, approved by the federal Food and Drug Administration and prescribed by an insured's treating physician, in multiple assay ranges as applicable, including from a 340B Program affiliated with a hemophilia treatment center. No vendor, pharmacist or provider shall make any substitution for a blood clotting product without the prior approval of such treating physician;

(B) All ancillary infusion equipment and supplies, including from a 340B Program affiliated with a hemophilia treatment center; and

(C) Nursing services provided in the home setting to assist an insured in the reconstitution and administration of blood clotting factors;

(2) Shall provide coverage for physician services for the treatment of bleeding disorders provided to an insured with a bleeding disorder or a suspected bleeding disorder and for services provided at a hemophilia treatment center to such insured for such treatment; and

(3) Shall provide coverage for clinical laboratory services at a clinical coagulation laboratory that an insured's treating physician determines are medically necessary for the screening, diagnosis and treatment of a bleeding disorder or a suspected bleeding disorder.

(b) If an insurer, health care center or other entity providing coverage of the type specified in subsection (a) of this section requires preauthorization for such blood clotting products, such insurer, health care center or other entity shall complete the preauthorization not later

than twenty-four hours or one business day, whichever is later, from the time or date the insurer, health care center or other entity receives the preauthorization request. If the circumstances are deemed urgent by the insured's treating physician, the insurer, health care center or other entity shall provide the preauthorization upon request by such physician.

Sec. 4. (NEW) (*Effective January 1, 2011*) Each vendor, pharmacy or provider that dispenses blood clotting products to an insured shall:

(1) Maintain necessary records and documentation, as prescribed by the Commissioner of Consumer Protection;

(2) Provide to an insured, upon request, the costs that will be billed to the insurer for blood clotting products, ancillary infusion equipment and supplies or nursing services set forth in sections 2 and 3 of this act;

(3) Provide to an insured, upon request, the anticipated coinsurance, copayment, deductible or other out-of-pocket expense to be imposed on the insured for blood clotting products, ancillary infusion equipment and supplies or nursing services set forth in sections 2 and 3 of this act;

(4) Provide administrative assistance to an insured to obtain payment or reimbursement for blood clotting products, ancillary infusion equipment and supplies or nursing services set forth in sections 2 and 3 of this act; and

(5) Provide to an insured notification of recalls and product withdrawals of blood clotting products and ancillary infusion equipment or supplies, immediately upon receiving notice of such recalls and product withdrawals.

Sec. 5. Section 20-619 of the general statutes is repealed and the following is substituted in lieu thereof (*Effective January 1, 2011*):

(a) For the purposes of section 20-579 and this section:

(1) "Brand name" means the proprietary or trade name selected by the manufacturer and placed upon a drug product, its container, label or wrapping at the time of packaging;

(2) "Generic name" means the established name designated in the official United States Pharmacopoeia/National Formulary, official Homeopathic Pharmacopoeia of the United States, or official United States adopted names or any supplement to any of them;

(3) "Therapeutically equivalent" means drug products that are approved under the provisions of the federal Food, Drug and Cosmetics Act for interstate distribution and that will provide essentially the same efficacy and toxicity when administered to an individual in the same dosage regimen; and

(4) "Dosage form" means the physical formulation or medium in which the product is intended, manufactured and made available for use, including, but not limited to, tablets, capsules, oral solutions, aerosol, inhalers, gels, lotions, creams, ointments, transdermals and suppositories, and the particular form of any physical formulation or medium that uses a specific technology or mechanism to control, enhance or direct the release, targeting, systemic absorption, or other delivery of a dosage regimen in the body.

(b) Except as limited by subsections (c) and (e) of this section, unless the purchaser instructs otherwise, the pharmacist may substitute a generic drug product with the same strength, quantity, dose and dosage form as the prescribed drug product which is, in the pharmacist's professional opinion, therapeutically equivalent. When the prescribing practitioner is not reasonably available for consultation and the prescribed drug does not use a unique delivery system technology, the pharmacist may substitute an oral tablet, capsule or liquid form of the prescribed drug as long as the form dispensed has the same strength, dose and dose schedule and is therapeutically equivalent to the drug prescribed. The pharmacist shall inform the patient or a representative of the patient, and the practitioner of the

substitution at the earliest reasonable time.

(c) A prescribing practitioner may specify in writing or by a telephonic or other electronic communication that there shall be no substitution for the specified brand name drug product in any prescription, provided (1) in any prescription for a Medicaid, state-administered general assistance, or ConnPACE recipient, such practitioner specifies the basis on which the brand name drug product and dosage form is medically necessary in comparison to a chemically equivalent generic drug product substitution, and (2) the phrase "BRAND MEDICALLY NECESSARY", shall be in the practitioner's handwriting on the prescription form or on an electronically-produced copy of the prescription form or, if the prohibition was communicated by telephonic or other electronic communication that did not reproduce the practitioner's handwriting, a statement to that effect appears on the form. The phrase "BRAND MEDICALLY NECESSARY" shall not be preprinted or stamped or initialed on the form. If the practitioner specifies by telephonic or other electronic communication that did not reproduce the practitioner's handwriting that there shall be no substitution for the specified brand name drug product in any prescription for a Medicaid, state-administered general assistance, or ConnPACE recipient, written certification in the practitioner's handwriting bearing the phrase "BRAND MEDICALLY NECESSARY" shall be sent to the dispensing pharmacy within ten days.

(d) Each pharmacy shall post a sign in a location easily seen by patrons at the counter where prescriptions are dispensed stating that, "THIS PHARMACY MAY BE ABLE TO SUBSTITUTE A LESS EXPENSIVE DRUG PRODUCT WHICH IS THERAPEUTICALLY EQUIVALENT TO THE ONE PRESCRIBED BY YOUR DOCTOR UNLESS YOU DO NOT APPROVE." The printing on the sign shall be in block letters not less than one inch in height.

(e) A pharmacist may substitute a drug product under subsection (b) of this section only when there will be a savings in cost passed on

to the purchaser. The pharmacist shall disclose the amount of the savings at the request of the patient.

(f) Except as provided in subsection (g) of this section, when a pharmacist dispenses a substitute drug product as authorized by subsection (b) of this section, the pharmacist shall label the prescription container with the name of the dispensed drug product. If the dispensed drug product does not have a brand name, the prescription label shall indicate the generic name of the drug product dispensed along with the name of the drug manufacturer or distributor.

(g) A prescription dispensed by a pharmacist shall bear upon the label the name of the drug in the container unless the prescribing practitioner writes "DO NOT LABEL", or words of similar import, on the prescription or so designates in an oral or electronic transmission of the prescription.

(h) Neither the failure to instruct by the purchaser as provided in subsection (b) of this section nor the fact that a sign has been posted as provided in subsection (d) of this section shall be a defense on the part of a pharmacist against a suit brought by any such purchaser.

(i) A pharmacist shall not make any substitution for a blood clotting product, as defined in section 1 of this act, without the prior approval of the prescribing practitioner.

[(i)**]** (j) The commissioner, with the advice and assistance of the commission, shall adopt regulations, in accordance with chapter 54, to carry out the provisions of this section.

This act shall take effect as follows and shall amend the following sections:		
Section 1	*January 1, 2011*	New section
Sec. 2	*January 1, 2011*	New section
Sec. 3	*January 1, 2011*	New section

Sec. 4	*January 1, 2011*	New section
Sec. 5	*January 1, 2011*	20-619

Statement of Purpose:

To improve access to appropriate medical care for persons with bleeding disorders.

[Proposed deletions are enclosed in brackets. Proposed additions are indicated by underline, except that when the entire text of a bill or resolution or a section of a bill or resolution is new, it is not underlined.]